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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/164,862 10/01/98 PRICE

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EXAMINER

HUNT, J

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

03/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/164,862

Applicant(s)

Price et al.

Examiner

Jennifer Hunt

Group Art Unit

1642



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-18, 38, 39, and 47-62 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-18, 38, 39, and 47-62 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1642

Continued Prosecution Application

1. The request filed on 11-29-2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/164,862 is acceptable and a CPA has been established. An action on the CPA follows.
2. Acknowledgment is made of applicant's cancellation of non-elected claims 19-37 and 40-46. Claims 1-18, 38-39, and 47-62 are pending in the application and currently under consideration.

Information Disclosure Statement

3. References AT and ABB have been received and an updated and the appropriate updated page of the initialed 1449 is enclosed with this Office Action.

Sequence Compliance

4. The corrected sequence submission has been received and entered. The case is now in sequence compliance.

Claim Rejections Withdrawn

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5. The rejection of claim 1 for the vague and indefinite recitation of “a adrenal gland cancer” is withdrawn in light of the amendments thereto.
6. The rejection of claim 50 for having an improper Markush group is withdrawn in light of the amendments thereto.

Claim Rejections Maintained/New Grounds of Rejection

7. Claims 38 and 51 are improper because they appear to contain a typographical error.
In claim 38, line 2 of the claim contains “::” which it appears should be “:”.
In claim 51, line 2 of the claim recites “and” ovarian cancer. It appears that the claim should recite “an” ovarian cancer.
Appropriate correction is required.
8. Claims 1-8 and 47-62 are improper because it cannot be determined what sample is being tested, what sample is the control, and from which sample/correlations the various correlations are determined. The methods should clearly set forth what samples are being tested, what tests are performed on the different samples, and what specific determinations and comparisons are made. Clarification is required.
9. Claims 1-18 are incomplete because they omit essential steps. See MPEP § 2172.01.
While all of the technical details of the method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is practiced.

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The minimum requirement for method steps should at least include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized and a correlation step describing how the results of the assay allow the determination. In the instant case, the correlation step does not correlate to the preamble of the claim. The preamble recites “a method for estimating length of survival”, while the correlation step is drawn to “determining reduced survival”.

10. Claims 10 and 49 are improper because they contain an improper Markush Group. The appropriate Markush format is “selected from the group consisting of....and”. Deletion of “or” and substitution therefor of --and-- would obviate this rejection.

11. Claim 11 is unclear in the recitation of “level” and “immunohistochemical staining”. It is not clear how immunohistochemical staining can be used in a quantitative method, to determine “levels”.

12. Further, claim 11 is unclear in that it cannot be determined how cells comprise a biological sample. It appears that the claim should recite that the cells are comprised within a biological sample, or a biological sample comprising cells which are...

13. Claim 38 is unclear in the recitation of a “possible” recurrence” of cancer. The metes and bounds of a “possible recurrence” cannot be determined. It is not clear what would constitute a “possible recurrence” and what would not.

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14. Claim 39 is unclear in the recitation of a “multiplicity of instances”. The metes and bounds of a multiplicity of instances cannot be determined. It is not clear what would be considered a “multiplicity” and what would not.

15. The rejection of claim 47 for the vague and indefinite recitation of a “statistically significant difference” is maintained for reasons of record, as applicant has neither argued the rejection, or amended the claims.

16. Claim 48 is unclear in the recitation of a “tissue affected by cancer”. The metes and bounds of a tissue affected by cancer of instances cannot be determined. It is not clear what would be considered a “tissue affected by cancer” and what would not. For example, would non-cancerous peripheral tissue be included? Non-peripheral tissue which was affected by systemic changes induced by the cancer?

17. Claim 49 is unclear in the recitation of “whole blood”. It is not clear if the assay is to be conducted on whole blood, or if the blood is to be clotted and the serum is to be tested. Further clarification is required.

18. The rejection of claims 1, 9-13, 15-17, 38, 39, 47-50, 52, 56-57, and 59-61 under 35 U.S.C. 102(b) as being anticipated by Johansen et al., European Journal of Cancer, Vol. 31A, No. 9, pp1437-1442, 1995 is maintained for reasons of record, as applicant has neither argued the rejection, nor amended the claims.

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19. The rejection of claims 1, 4-10, 11-18, 47-49, and 56-62 under 35 U.S.C. 102(e) as being anticipated by Robbins et al., US Patent 5,726,061, filed 10/8/1996, issued 3/10/98 is maintained for reasons of record, as applicant has neither argued the rejection, nor amended the claims.

20. The rejection of claims 1-18, 47-62 as being unpatentable over Johansen et al, in view of Maggio et al., US Patent 4,828,981, issued 5/9/1989, or Harlow et al., Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, 1988, pages 148-212, or Price et al., WO 95/01995, 1/19/1995 is maintained for reasons of record, as applicant has neither argued the rejection, nor amended the claims.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Hunt, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.

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Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**anthony.caputa@uspto.gov**].

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Hunt

March 26, 2001


BRENDA BRUMBACK
PATENT EXAMINER